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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/551,977	04/14/2000	John M. Polo	930049.489/1593.004	2230

7590 01/27/2003

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EXAMINER

LI, BAO Q

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 01/27/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/551,977

Applicant(s)

POLO ET AL.

Examiner

Bao Qun Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17, 19 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17, 19 and 21-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Claims 17 and 19-23 are pending.

RCE

A request for continued examination filed on paper No. 2, Nov. 13, 2002, under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions of RCE and amendments filed on 09/10/2002 and 01/21/2003 have been entered.

RCE has been established. An action on the RCE follows.

Response to Amendment

This is a response to the amendment paper No. 19, filed 09/10/02 and amendment paper No. 23, filed on 01/21/2003. The specification and claims 17, 19 and 21-23 have been amended. Claims 1-16, 18 and 24-37 have been canceled. Claims 17 and 19-23 are considered before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Sequence requirements

This application contains sequence disclosures on **page 47** that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Full compliance with the sequence rules is required in response to this Office Action. A complete response to this office action should include both compliance with the sequence rules and a response to the Office Action set forth below. Failure to fully comply with **both** these

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requirements in the time period set forth in this office action will be held non-responsive.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Applicant's arguments with respect to claim 17 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

3. Claims 17 and 21-23 are still rejected under 35 U.S.C. 112, first paragraph on the same ground as stated in the previous Office Action, because the specification, while being enabling for having a recombinant Sindbis virus particle with only one amino acid substitution mutation (Gly to Gln) at the amino acid position of 160, which is able to infect human dendritic cell, does not reasonably provide enablement for having any or all recombinant alphavirus particle except the strain of ATCC#VR-2526 comprising any or all kind of an amino acid mutations at the region from 158 to 162 of the amino acid residues that are all able to infect human dendritic cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.
4. Applicants traverse the rejection and submit that the cited references are all directed to use the infection of murine cells and they are not relevant to the infection of human dendritic cells, the pending claims are directed to particles that infect human DC and the problem appeared in Tucker's cells may not arise in human host cells. Applicants further assert that Patent Office is not a regulatory agency in determining the safety. Finally, Applicant strongly disagreed that scope of an applicants' claims is only limited to those embodiment, which are actually exemplified in the specification because the teachings of the specification readily enable one of skill in the art to select and identify mutation affecting amino acid residues at about 158 to 162 of

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the E2 gene that confer the human dendretic cell tropic phenotype and incorporate said mutation into recombinant alphavirus particle.

5. Applicants argument has been respectfully considered; however, it is not found persuasive because the specification does not provide enough evidence to support that the any or all kinds of mutation including deletion, insertion, or other substitute mutations rather than actually exemplified in the specification at the all 5 possible positions from 158 to 162 is enabled and do not cause any serious problems as discovered by Tucker et al. and MacDonald. In this context, the references of Tucker et al. and MacDonald et al. cited by the Office is relevant because they teach that mutation of alphavirus genome is possible to produce some unexpected result that unable to make the aphavirus as an efficient gene delivery vehicle due to the neurotoxicity and change the DC tropism to non-DC tropism. This is not only a safety issue, but also an enablement issue.

6. Regarding to Applicants' argument that claimed invention should not only limited to those embodiment, which are actually exemplified in the specification, Office notices that the enablement issue of current Application does not only relay on what Applicants have described as a method for making a virus particle a alphavirus with so many possible mutations, it more relay on whether a structure and its associated function has been disclosed in the specification. However, the specification does not describe the structures and the functions for each or all possible unknown virus particles that have not been isolated. The results for making all those possible mutation for the alphavirus as a human DC-tropic virus are very unpredictable and chances for succeed of making each or all claimed alphavirus particle enabled are unexpected too. Applicants are suggested t provide more evidence that support other alphaviruses with claimed mutation at all five positions are enable to infect human DC. Otherwise, the rejection is maintained.

New Grounds of Rejections:

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claims 17, 19 and 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 17 is vague in that the structure characteristic of “a recombinant alphavirus particle” are not clearly defined because the claim uses an open language of “comprising an amino acid mutation”, which fails to define whether the intended virus particle only has one mutation at the particular position as listed in the claim or the claimed one mutation is just a mutation in the particular position, other mutation(s) may still exist beside this particular one. If Applicant wish to claim the virus particle contains only one mutation at the claimed position, please amend the claim with more clear language, such as “consisting of only one mutation” Or Applicants are suggested to amend the claim as “said alphavirus particle comprising a mutated E2 glycoprotein, which consists of only one mutation at the position” This affects the dependent claims 19 and 21-23.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 17 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Glasgow et al. (Virology 1991, Vol. 185, pp. 741-748).

Glasgow et al. disclose a recombinant Semliki Forest virus (SFV) comprises two amino acids substitute mutations at its glycoprotein E2, which include an amino acid substitute amino acid mutation from Glu to Lys at the position of 162 (See entire document). Therefore, the claimed invention is anticipated by the cited prior art.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

13. Claims 17 and 21 are rejected under 35 U.S.C. 102(a) as being anticipated by Glomb-Reinmund et al. (J. Virol. 1998, Vol. 72, pp. 4281-4287).

14. Glomb-Reinmund et al. disclose a mutated alphavirus particle of Semliki Forest Virus (SFV) comprising an amino acid substitution mutation at the position of 162 of the E2 region, in which the amino acid lysine is substituted to the glutamine (se Fig 7 and lines 18-26 on left col. of page 4285. Therefore, the claimed invention is anticipated by the cited reference.

15. Glasgow et al. and Glomb-Reimund et al. are silence for the ability of the virus for infecting human dendretic cell. However, this recitation appears in the preamble, the recitation of “infects human dendretic cell” has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). In the instant case, the preamble language of “ infecting dendretic cell” does not indicate that the claimed virus has any structural difference to the disclosure of the prior art. Applicants’ attention is directed to the following discussion in the MPEP:

The claim preamble must be read in the context of the entire claim. The determination of whether preamble recitations are structural limitations or mere statements of purpose or use “can be resolved only on review of the entirety of the [record] to gain an understanding of what the inventors actually invented and intended to encompass by the claim.” Corning Glass Works, 868 F.2d at 1257, 9 USPQ2d at 1966. If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any

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distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also Rowe v. Dror, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) ("where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation"); Kropa v. Robie, 187 F.2d at 152, 88 USPQ2d at 480-81 (preamble is not a limitation where claim is directed to a product and the preamble merely recites a property inherent in an old product defined by the remainder of the claim); STX LLC. v. Brine, 211 F.3d 588, 591, 54 USPQ2d 1347, 1350 (Fed. Cir. 2000) (holding that the preamble phrase "which provides improved playing and handling characteristics" in a claim drawn to a head for a lacrosse stick was not a claim limitation.

Conclusion

No claims are allowed.

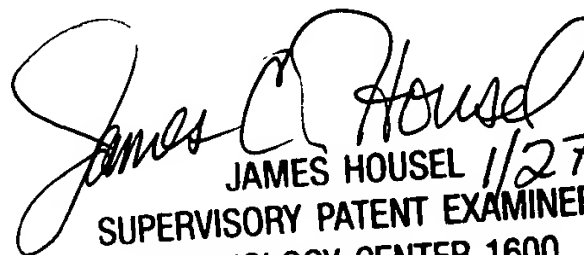
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 8:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

January 24, 2003


JAMES HOUSEL 1/27/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600